K052011

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary AUG 10 2005

NAME OF FIRM:
I.T.S. Implantat-Technologie-Systeme GmbH
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Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Pilonplate with Angular Stability

COMMON NAME: Bone Plate System

CLASSIFICATION: Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030).

DEVICE PRODUCT CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes Pilon Plate (**K020602**)
DePuy/Ace TIMAX Pilon Plate **(K982347)**
Synthes LCP Distal Tibia Plates **(K013248)**
Synthes (USA) Medial Distal Tibia Plates **(K001945)**
Link Small Bone Plates (May Anatomical Plate) **(K854825)**
Zimmer Periarticular Plating System

DEVICE DESCRIPTION:
The I.T.S. Pilonplate with Angular Stability is a low-profile universal left and right titanium 4, 6, and 8 hole plate with various length 4.2mm Cancellous self-tapping and head locking stabilization screws. Additional 4.5mm Cortical screws of various lengths are self-tapping and secure the Pilonplate to the shaft of the tibia bone. The Pilonplate is made from CP titanium according to ASTM F 67-00 and the screws are made from 6-4 alloyed titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

INTENDED USE:
Indications for Use include fixation of complex intra- and extra- articular fractures, osteotomies, high medial malleollar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The I.T.S. Pilonplate with Angular Stability is substantially equivalent to the Synthes, DePuy/ACE, Link America, and Zimmer bone plate systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:
The I.T.S. Pilonplate with Angular Stability is shown to be safe and effective for use in fracture fixation of the distal tibia in the leg.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 2005

I.T.X. Implantat-Technologie-Systeme GmbH
c/o Mr. Albert Lippincott III
U.S. Agent and Official Correspondent for I.T.S.
Implantat-Technologie-Systeme GmbH
Engineering Consulting Services, Inc.
3150 E 200th Street
Prior Lake, Minnesota 55372

Re: K052011
Trade/Device Name: Pilonplate with Angular Stability
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 15, 2005
Received: July 25, 2005

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) NUMBER: K052011

DEVICE NAME: **PILONPLATE WITH ANGULAR STABILITY**

INDICATIONS FOR USE:

The I.T.S. Pilonplate with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal tibia in the leg.

Indications for Use include fixation of complex intra- and extra-articular fractures, osteotomies, high medial malleollar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation (ODE)
CDRH

510(k) Number K052011